

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

SWA-XXX

U.S. APPLICATION NO. (If known, see 37 CFR 1.5

09/806110

INTERNATIONAL APPLICATION NO.  
PCT/CA99/00895INTERNATIONAL FILING DATE  
27 SEPT 1999PRIORITY DATE CLAIMED  
28 SEPT 1998

## TITLE OF INVENTION

USE OF PEX IN THE TREATMENT OF METABOLIC BONE DISEASES

## APPLICANT(S) FOR DO/EO/US

ANDREW C. KARAPLIS, ET. AL.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau. (Convenience copy provided)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

## Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: International Preliminary Examination Report accompanied by annexes. (Convenience copy provided)

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) **09/806110** INTERNATIONAL APPLICATION NO. PCT/CA99/00895ATTORNEY'S DOCKET NUMBER  
SWA-XXX21. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**Neither international preliminary examination fee (37 CFR 1.482)  
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO  
and International Search Report not prepared by the EPO or JPO. .... **\$1000.00**International preliminary examination fee (37 CFR 1.482) not paid to  
USPTO but International Search Report prepared by the EPO or JPO ..... **\$860.00**International preliminary examination fee (37 CFR 1.482) not paid to USPTO  
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... **\$710.00**International preliminary examination fee (37 CFR 1.482) paid to USPTO  
but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... **\$690.00**International preliminary examination fee (37 CFR 1.482) paid to USPTO  
and all claims satisfied provisions of PCT Article 33(1)-(4) ..... **\$100.00****ENTER APPROPRIATE BASIC FEE AMOUNT =****CALCULATIONS PTO USE ONLY**

\$ 860.00

Surcharge of **\$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30  
months from the earliest claimed priority date (37 CFR 1.492(e)).

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	- 20 =	0	x <b>\$18.00</b>
Independent claims	- 3 =	3	x <b>\$80.00</b>
			+ <b>\$270.00</b>

MULTIPLE DEPENDENT CLAIM(S) (if applicable)

**TOTAL OF ABOVE CALCULATIONS =**

\$ 1,100.00

☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above  
are reduced by 1/2.**SUBTOTAL =**

\$ 950.00

Processing fee of **\$130.00** for furnishing the English translation later than ☐ 20 ☐ 30  
months from the earliest claimed priority date (37 CFR 1.492(f)).**TOTAL NATIONAL FEE =**

\$ 950.0000

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be  
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **\$40.00** per property +**TOTAL FEES ENCLOSED =**

\$ 990.0000

Amount to be  
refunded:

\$

charged:

\$

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 08-0219 in the amount of \$ 1,990.000 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any  
overpayment to Deposit Account No. 08-0219. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card  
information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR  
1.137 (a) or (b)) must be filed and granted to restore the application to pending status.SEND ALL CORRESPONDENCE TO: WAYNE A. KEOWN, PH.D  
HALE AND DORR, LLP  
60 STATE STREET  
BOSTON, MA 02109

SIGNATURE

WAYNE A. KEOWN, PH.D

NAME

33,923

REGISTRATION NUMBER

09/806110

JC08 Rec'd PCT/PTO 28 MAR 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Andrew C. Karaplis, et.al.

Serial No.: TBA

Examiner: TBA

Filed: Herewith

Group Art Unit: TBA

For: Use of PEX in the treatment of Metabolic Bone Diseases

Attorney Docket No.:

Box PCT  
Commissioner for Patents  
Washington, D.C. 20231

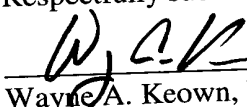
STATEMENT UNDER 37 C.F.R. §1.821(f)

Sir:

The diskette enclosed herewith contains a computer readable form of the Sequence Listing for the above-referenced patent application. The material on this diskette is identical in substance to the Sequence Listing filed herewith. The computer readable form of the Sequence Listing contained on this diskette is understood to comply with the requirements of §1.821(f).

Dated: March 28, 2001

Respectfully submitted,

  
Wayne A. Keown, Ph.D.  
Registration No. 33,923  
Attorney for Applicants

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March 28, 2001

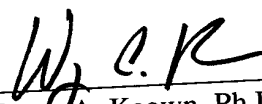
BOX PCT  
Assistant Commissioner for Patents  
Washington, DC 20231

Re: United State National Stage of PCT Application  
NO. PCT/CA99/00895 "ANDREW C. KARAPLIS, ET. AL"  
Our Ref.: SWA-XXX

Dear Sirs:

I enclose herewith the necessary papers to begin the national examination procedure for the above-referenced PCT application in the United States.

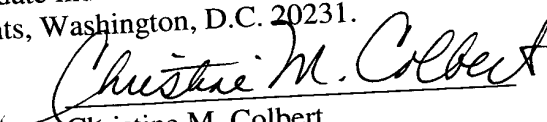
Respectfully submitted,

  
Wayne A. Keown, Ph.D.  
Registration No. 32,923

"Express Mail" mailing label number  
Date of Deposit March 28, 2001

EL52166643345

I hereby certify that the attached Transmittal Letter to the U.S. Designated Office;  
~~International Application PCT/CA99/00895; Declaration and Power of Attorney~~  
~~Verified Statement Concerning Small Entity Status; Small Business Concern and~~  
~~Independent Inventor's Copy of Preliminary Amendment; Information Disclosure~~  
~~Statement including Form PTO 1449 and References~~  
being deposited with the United States Postal Service "Express Mail Post Office to  
Address" service under 37 CFR 1.10 on the date indicated above and is addressed to the  
Box PCT, Assistant Commissioner for Patents, Washington, D.C. 20231.

  
Christine M. Colbert